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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,276	03/07/2001	John W. Erickson	207596	9981

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,276	ERICKSON ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47 and 49-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47 and 49-78* is/are rejected.

7)☒ Claim(s) *67* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/21/2000, 05/10/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 67-78 have been entered. Claims 1-46 and 48 are canceled. Claims 47 and 49-78 are under examination.

Oath/Declaration

2. The objection for a defective oath is withdrawn in view of Applicant's amendment.

Information Disclosure Statement

3. Applicant's submission of a replacement IDS and references is greatly appreciated. Attached to this office action is a copy of Applicant's submitted IDS(es), signed and initial by the Examiner.

Claim Objections

4. The claim objection against claim 63 for being in improper dependent form is withdrawn in view of Applicant's amendment.

5. Claim 68 is objected to because of the following recitation "a group of the formula". Currently, as written, the claim only recites a formula, not a group of formulas.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 47 and 49-66 remains and newly added claims 67-78 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the composition/compound that is used in the method claims, does not reasonably provide

enablement for a method of preventing the development of drug resistance in an HIV infected mammal or to treat a mutant retroviral infection in a mammal infected with a mutant retrovirus with the administration of a drug resistance-inhibiting compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/use the invention commensurate in scope with these claims.

In response to the enablement rejection set forth in the previous office action, Applicant submits the following: The instantly claimed invention is enabling by the specification. The specification teaches how to prepare, characterize, and biologically test the compounds that is recited it the claims. Further, the specification teaches methods of formulating and therapeutically administer the compounds used in the claimed invention. Additionally, Applicant notes that the specification provides data that demonstrate the biological efficacy of the recited compounds; wherein the biological efficacy is concluded upon data that demonstrates the potent, broad spectrum antiviral activity of exemplary compounds against a panel of multiply mutated, multi-drug resistant HIV isolated form HIV-infected humans. The specification also provides data that demonstrates the potent inhibitory activity of exemplary compounds against HIV proteases that contain deleterious mutations associated with drug resistance. Furthermore, the specification contains in vivo data that demonstrates the high blood levels achieved by oral administration of an exemplary compound, high potency can be maintained even in the presence of excessive amounts of human binding proteins.

The Examiner has considered the above-submitted points, however, it is found not persuasive. This is so because the data that is demonstrated by the working examples, and the teachings of how to prepare and characterize the compounds that is recited in the claimed method does not enable one skilled in the art to practice (use) the claimed invention without an undue burden of experimentation. Applicant's disclosure does not commensurate with the invention that is instantly claimed. The instantly claimed invention is directed at a method of preventing the development of drug resistance in an HIV-infected mammal and treating mutant retroviral infections via the administration of the drug that Applicant denotes as Formula I. In order to provide an enabling disclosure for the claimed methods, Applicant is required to demonstrate that the administration of Formula I accomplishes the task that is required of the claimed method, prevents the development of drug resistance and treats mutant retroviral infections. Such demonstration can be accomplished via in vitro or in vivo. Since the instantly claimed invention is directed at an in vivo use, Applicant must demonstrate a correlation or nexus between the in vitro data and an in vivo use. However, no such demonstration can be found within the disclosure of the instantly claimed method. Additionally, Applicant's arrival at the conclusion that because the compound denoted as Formula I have specific observed activities, it **SHOULD** [with emphasis added] prevent the development of drug resistance and treats mutant retroviral infections is not adequate to enable one skilled in the art to practice the claimed invention without an undue burden of experimentation.

While it is acknowledge that Applicant submits that a complex experiment does not equate to an undue burden of experimentation. The Examiner agrees with Applicant, however, Applicant has taken the Examiners conclusion that an undue burden of experimentation would be required of one skilled in the art to practice the instantly claimed invention out of context. The Examiner's conclusion of undue experimentation is not based on the complexity of the experimentation that is required on the part of the skilled artisan. Nor is the Examiner's assertion of undue burden is not made solely on the basis of the quantity of experimentation. As noted in the previous office action, the undue burden of experimentation is concluded upon an in-depth analysis using the Wands factors. It is from the culmination of these factors, recited in the previous office action, that the Examiner concludes that an undue burden of experimentation would be required of the skilled artisan.

Furthermore, Applicant's assertion that the fact that HIV may ultimately be capable of developing resistance to virtually any anti-HIV agent does not renders Applicant's invention inoperable and that since the claimed methods do not require absolute preclusion has been fully considered. However, Applicant's assertion is not found persuasive. Nowhere in the instantly recited claim is there any indication that the instantly claimed invention does not require absolute preclusion of resistance or mutant retroviral infection. Currently as written, the methods are directed to treating a mutant retroviral infection in a mammal and preventing the development of drug resistance in an HIV-infected mammal.

Moreover, Applicant argues that the term prevent itself is not necessarily absolute. The Examiner agrees with Applicant. However, the issue at hand is not if the instantly claimed method prevents the development of drug resistance, the same is true for treating a mutant retroviral infection, 100% of the time. The issue at hand is that Applicant has not provided any convincing evidence that the administration of a compound denoted as Formula I prevents the development of drug resistance and treats mutant retroviral infections.

In addition to the above arguments submitted by Applicant, Applicant also submitted a Declaration under 37 C.F.R § 1.132, by Dr. Hiroaki Mitsuya.

Dr. Mitsuya declaration has been fully considered. However, the statements made by Dr. Mitsuya are not found persuasive. This is so because Dr. Mitsuya conclusion that the compounds that are used in the claimed method should effectively inhibit new strains of HIV that emerge in humans undergoing anti-HIV therapy, should significantly delay the emergence of HIV resistance in vivo, and should be therapeutically effective for treating existing infections with multi-drug resistance, are not supported by any evidence. The statements of Dr. Mitsuya are conclusory statements that are not based on any findings that commensurate with the scope of the claimed invention. Furthermore, Dr. Mitsuya's statement indicates Applicant has not shown that the administration of the compound denoted as Formula I prevents the development of drug resistance and treats mutant retroviral infections, as evidenced by Dr. Mitsuya's use of the word "should", the same is noted in Applicant's response to the office action, see last full paragraph of page 18.

Therefore, in view of Applicant's arguments and Dr. Mitsuya's declaration, the instantly claimed inventions remains rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0169.

E.Le
Emily Le

James C. Housel 7/12/04
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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